

REMARKS

Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, 28, 29, 31, 34, 36, 39-41. 46, 49, 51, 61, 64, 66, 67 and 69-77 and 79 are now in the application. Claims 29, 31, 33, 34, 36, 39-41. 46, 49, 51, 61, 64, 66, 67 and 69-78 are directed to the elected invention. Claims 1, 2, 4, 8, 12, 13, 15, 17, 20, and 28 are directed to non-elected invention and may be cancelled by the examiner upon the allowance of the claims directed to the elected invention.

Claim 29 has been amended to include recitations from claim 33 along with modifying language concerning the claimed Markush group. Accordingly, claim 33 has been cancelled without prejudice or disclaimer. Claim 29 has also been amended to recite a content of the polyglycerol fatty acid ester disclosed in the specification at page 22, lines 12-27 of the specification. Accordingly, claim 78 has been cancelled without prejudice or disclaimer. Claim 29 has been amended by deleting the recitations concerning the amount of Vitamin E that was added in a prior response. Newly presented claim 79 recites the Vitamin E content cancelled from claim 29. Claim 29 has also been amended to recite “at least one member selected from the group consisting of a fat component, an oil component and a polyol” in place of “a fat component, an oil component and/or a polyol” for purposes of clarification and not to limit its scope. Claims 36 and 41 have been amended to recite “total weight of the composition minus a weight of” in place of “the system excluding” for purposes of clarification and not to limit their scope. Claim 46 has been amended to correct the formula (1). Claim 61 has been amended to recite “wherein a percent” in place of “wherein the percent” and to recite “at least one member selected from the group consisting of a fat component, an oil component and a polyol” in place of “a fat component, an oil component and/or a polyol” for purposes of clarification and not to limit its scope. The amendments to the claims and newly presented claims do not introduce any new matter.

The rejection of claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67, and 69-78 under 35 USC 112, second paragraph and the comments concerning the issue of 35 USC 112, second paragraph in the Advisory Action have been addressed by the above amendments to

the claims. For instance, claims 29, 33 and 61 have been amended to recite “at least one member selected from the group consisting of a fat component, an oil component and a polyol” in place of “a fat component, an oil component and/or a polyol”. Also, the Markush group of the fat or oil has been properly and clearly recited in claim 29. The issue of lack of antecedent basis has been addressed by the above amendments to the claims.

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67, and 69-78 were rejected under 35 USC 103(a) as being obvious WO 01/52822 to Chopra in view of US Patent 4,751,241 to Motoyama et al. The cited references do not render obvious the present invention.

The composition of the present invention comprises 1) reduced coenzyme Q₁₀, 2) at least one member selected from the group consisting of a fat component, an oil component and a polyol, and 3) a polyglycerol fatty acid ester, with the claimed specific contents. By the above specific composition, the present invention makes it possible to achieve the reduced coenzyme Q₁₀-containing composition having good absorbability without inhibiting the reduced coenzyme Q₁₀-stabilizing effect against oxidation.

As disclosed on page 4, line 35 to page 5, line 24 in the specification, the composition of the present invention can have simultaneously both good stability of reduced coenzyme Q₁₀ and a high-level absorbability in a living body. First of all, the present inventors found that reduced coenzyme Q₁₀ is protected against oxidation by molecular oxygen and stabilized in a surprisingly favorable manner in the presence of a fat and/or oil component and/or a polyol without preparing any complicated and troublesome composition. Secondly, the present inventors also found the following: while the addition of Tween and Span species (surfactants (emulsifiers)) in wide use markedly decreases the above-mentioned reduced coenzyme Q₁₀-stabilizing effect of a fat and/or oil component and/or polyol, the addition of polyglycerol fatty acid esters surprisingly has little influence on the stabilizing effect of the fat and/or oil component and/or polyol and such esters serve as very favorable surfactants (emulsifiers). Namely, the addition of the polyglycerol fatty acid ester enhances absorbability of reduced coenzyme Q₁₀ in the living body without inhibiting

the reduced coenzyme Q₁₀-stabilizing effect of the fat and/or oil component and/or polyol so that reduced coenzyme Q₁₀ can be stably maintained.

As appreciated by the Examiner, Chopra does not disclose the polyglycerol fatty acid ester employed according to the present invention. In addition, the components other than the polyglycerol fatty acid ester in the composition of the present invention also differ from those in Chopra. Since the composition of Chopra contains a large quantity of Vitamin E or Tween/Span, the composition cannot stably maintain reduced coenzyme Q₁₀ without a reducing agent. Thus, the composition of Chopra stably maintains reduced coenzyme Q₁₀ by using a reducing agent. On the other hand, by including the fat and/or oil component and/or the polyol, the composition of the present invention can stably maintain reduced coenzyme Q₁₀ whether or not the composition contains a reducing agent. Thus, Chopra neither discloses nor suggests that the composition of the present invention can stably maintain reduced coenzyme Q₁₀ by using the fat and/or oil component and/or the polyol.

Motoyama describes the polyglycerol ester of an unsaturated fatty acid, but Motoyama does not disclose the preferable relationship between the content of the polyglycerol ester of an unsaturated fatty acid and the content of the fat component, the oil component and/or the polyol in the composition. Most of Motoyama's Examples do not even use the fat component, the oil component or the polyol at all. Even when the fat component, the oil component or the polyol is used in Motoyama, the content of the component is considerably smaller than that of the ester of an unsaturated fatty acid. Along these lines, please see the attached sheet for an analysis of Motoyama's Examples.

Therefore, even if Chopra and Motoyama were combined, the present invention would still not be disclosed and is unobvious.

In addition, Motoyama only describes coenzyme Q₁₀ (ubidecarenone: oxidized coenzyme Q₁₀) on column 2, lines 55-56 and does not describe reduced coenzyme Q₁₀. Thus, since Motoyama uses oxidized coenzyme Q₁₀, which is already oxidized, Motoyama does not intend at all to maintain reduced coenzyme Q₁₀ stable with protecting it against oxidation. Moreover, Motoyama only describes that the polyglycerol ester of an unsaturated fatty acid is used in order to facilitate the

absorptivity of the drug. As mentioned on page 10 of the Office Action, in Motoyama, the dispersibility of drug formulations is stabilized by use of the polyglycerol fatty acid ester. Thus, Motoyama neither discloses nor suggests the effects of the present invention, in which reduced coenzyme Q₁₀ is stabilized against oxidation in the presence of a fat and/or oil component and/or a polyol and the addition of the polyglycerol fatty acid ester barely inhibits the reduced coenzyme Q₁₀-stabilizing effect of the fat and oil component and/or polyol.

As shown in the Declaration under 37 CFR 1.132 filed with the Response after Final Office Action, in the composition containing polyglycerol fatty acid and not higher than 30% by weight of Tween80 high stability of reduced coenzyme Q₁₀ was achieved, but in the composition containing higher than 30% by weight of Tween80 the stability of reduced coenzyme Q₁₀ was extremely inhibited. In addition, as shown in Examples 23-24 in the present specification, the composition containing no Tween80 also shows high stability of reduced coenzyme Q₁₀. However, Chopra and Motoyama neither disclose nor suggest such excellent effects of the present invention.

As mentioned above, the combination of Chopra and Motoyama neither discloses nor suggests that the composition can simultaneously have both good stability of reduced coenzyme Q₁₀ and a high-level absorbability in a living body by the specific constitution of the present invention. Consequently, the present invention would not have been suggested to one skilled in the art from the combination of Chopra and Motoyama, and it is unobvious.

Claims 29, 31, 33, 34, 36, 39-41, 46, 49, 51, 61, 62, 64, 66, 67, and 69-78 were provisionally rejected on the grounds of non-statutory obviousness-type double patenting over claims 16-19 of application SN 11/586,511. Claim 29 recites the amounts of Tween and/or Span, which are not recited in claim 16 of SN 11/586,511. Accordingly, it is requested that this rejection be withdrawn. This rejection if need be will be further addressed once the other rejections have been overcome.

In view of the above amendment, applicant believes the pending application is in condition for allowance.

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Respectfully submitted,

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